NEGOTIATED RULEMAKING COMMITTEE ON THE SHARED RISK EXCEPTION

MINUTES[1]

November Meeting
November 19-21, 1997

On November 19-21, the Negotiated Rulemaking Committee on the Shared Risk Exception met at the Hall of the States, Washington, D.C. (See **Attachment A** for a list of the Committee Members and/or their alternates attending the meeting.)

On November 19 and on the morning of November 20, the meeting focused primarily on a comprehensive proposal made by the Federal parties to the negotiations. (See **Attachment B.**) This proposal addresses the Shared Risk Exception, section 216 of the Health Insurance Portability and Accountability Act of 1996, and some related issues outside the scope of section 216 (identified in the proposal as "HHS Regulatory Authority"). **Attachment C** lists the Committee's issues, questions, and concerns related to the Federal proposal and recorded on flipcharts during the meeting.

On the afternoon of November 20, some Committee Members met in caucus to develop proposed modifications to the Federal proposal. Some of these proposed modifications were discussed on November 21 before the meeting adjourned. Further modifications will be submitted and addressed according to the schedule set out below on page 18.

These minutes first summarize the Federal agencies' general explanation of their proposal and some questions that arose regarding what consensus with this proposal would mean. The minutes then summarize, for each part in general and for each specific topic addressed in the proposal:

- any explanations or clarifications of the proposal by the Federal agencies;
- any matters the Federal agencies recognized need to be addressed further;
- major concerns about the proposal expressed by other parties;
- proposed modifications discussed at the meeting; and
- major concerns raised about the proposed modifications.

The last section of these minutes summarizes the next steps in the Committee's negotiations and the agenda for the December

[1] These minutes were prepared by the facilitators for the convenience of the Committee Members and should not be construed to represent the official position of the Committee or of any Member on what transpired at the meeting.

meeting.

Federal agencies' explanation of their proposal and Committee response

The OIG/HHS representative noted generally that the Federal proposal--

- was developed with input from the major Federal agencies with a stake in the rule, including the Office of Management and Budget;
- was offered because of the need to get a rule out quickly, with the hope that the proposal will move the Committee to consensus by the December meeting;
- represents an overall comprehensive approach to the larger policy issues regarding managed care arrangements, not just the section 216 issues;
- may alleviate tensions caused during Committee negotiations because section 216 does not address the larger issues; and
- reflects input from the Committee's participation.

He indicated that the Federal agencies are prepared to discuss the concepts in the proposal, to make adjustments, and to consider provisions on programs not addressed in the proposal (such as Medicaid and the Department of Defense CHAMPUS program). On the other hand, he made it clear that the package stands as a whole, that the Federal agencies would not feel comfortable expanding safe harbor protection beyond section 216 if there is a loose definition of "organization" or "substantial financial risk," and that the package as a whole is basically what the Federal agencies can live with.

He explained that, while Congress mandated publication of an interim final rule implementing section 216, the Secretary retains discretion about whether to promulgate a rule addressing related issues outside the scope of section 216. If the Secretary exercises that discretion, he explained, she must use notice and comment rulemaking under the Administrative Procedure Act. He indicated that if the Federal representatives are comfortable with the section 216 issues (specifically, "organization" and "substantial financial risk"), they would advocate that the Secretary publish a proposed rule addressing the related issues outside the scope of section 216 and would expect that she would likely do so. The proposed rule would be published at the same time as the interim final rule on section 216. He emphasized, however, that the Federal representatives' authority to negotiate about section 216 does not authorize them to obligate either themselves or the Secretary in any way with respect to issues outside the scope of section 216. Thus, he suggested that any Committee agreement could provide that the

outside parties' commitment not to file negative comments would be contingent on whether the Secretary does in fact publish a proposed rule on any larger issues addressed in a Committee consensus. He noted that there is precedent for such an agreement being developed through a negotiated rulemaking process.

When the proposal was first presented, the HHS/OIG representative indicated, in response to a question, that the outside parties would still be free to comment on a related proposed rule. This question was again raised at the end of the meeting. The following **concerns** were raised:

- If a Committee agreement might bind the outside parties not to file negative comments on the related proposed rule, as well as on the section 216 interim final rule, Committee Members would need to discuss this with their constituents, especially since they may be authorized to act only with respect to section 216.
- If any party may file negative comments on the related proposed rule, this could undercut the "buy-in" obtained by the Committee consensus on a comprehensive package.
- Outside parties might not want to agree to provisions that parties representing other interests might be successful in getting changed.

Thus, it was agreed that, **if the Federal agencies intend to seek an agreement not to submit negative comments on any related proposed rule, they will inform the facilitators as soon as possible. The facilitators will then notify Committee Members, who will discuss this with their constituents prior to the December meeting.**

The Committee also discussed whether its consensus would take the form of an agreement on basic concepts (with the IG to draft a rule with the same substance and effect) or an actual draft of the text of the rule, and possibly preamble language as well. The suggestion was made that the Committee may wish to focus on drafting text for key parts of the rule and the preamble, but agree to concepts for less controversial parts of the rule. Committee Members concurred in using the Federal proposal as a framework for continued negotiations.

The facilitators noted that the draft agreement language they had circulated to Committee Members (based primarily on the Committee's Organizational Groundrules) would need to be modified if any agreement not to submit negative comments is contingent on the Secretary's exercise of her discretionary regulatory authority. They offered to draft modified provisions to this effect.

FIRST PRONG

GENERAL

The Federal proposal has two parts. Committee Members referred to the first part of the proposal (**I. Managed Care Organizations under Medicare Capitation**) as the "first prong." This term has been used by the Committee at previous meetings to refer to the first part of the Shared Risk Exception in section 216 (protection from anti-kickback liability for remuneration pursuant to a written agreement between an eligible organization under section 1876 of the Social Security Act and an individual or entity providing items or services, or a combination thereof). The Federal agencies explained that their proposal (contingent on Secretarial approval) would expand the safe harbor protection beyond section 216 by including more "covered entities" than "eligible organizations" and by protecting downstream arrangements.

COVERED ENTITIES

The Federal proposal on what entities would be covered in the first prong is at page 1 of **Attachment B**. The Federal agencies clarified that--

- Federally qualified HMOs would be covered as "eligible organizations," even if they do not have a Medicare contract.
- Some Medicare+Choice organizations contracting with HCFA under new Medicare Part C would be covered, but fee-for-service (FFS) plans and medical savings accounts (MSAs) would not be covered.
- Possibly the CHAMPUS Tri-Care program and some Medicaid 1903(m) organizations should be covered as well (although State waivers raise questions about the appropriateness of covering all 1903(m) organizations).

Discussion at the meeting focused mainly on how to describe what Medicaid entities to cover. A caucus met to discuss this issue and reported that it was working on a specific proposal to resolve the issue.

Some Committee Members indicated that they were considering a proposal defining covered entities more broadly--for example, any organization paid in any Federal program (covered by the anti-kickback provision) where compensation is on a capitated basis for a comprehensive range of services. These Members indicated that they intend to work on a more specific proposal.

Other Members indicated that demonstration projects such as PACE

should be covered and that specific proposals about such projects would be offered. The IG representative indicated that the Federal agencies may not feel comfortable with covering such projects under the first prong.

"FIRST TIER" PROVIDERS

The Federal proposal on "first tier" providers (those with an agreement with the covered entity) is at page 1 of **Attachment B.** There was little discussion of this section of the proposal, other than a suggestion that section (D) be clarified to indicate that the limit on the provider claiming payment from Medicare would apply only to services within the Medicare contract.

"DOWNSTREAM" PROVIDERS

The Federal proposal on "downstream" providers for the first prong is at page 2 of **Attachment B**. The Federal agencies clarified that this provision (under the HHS regulatory authority) would protect arrangements downstream from an arrangement with a covered entity, whether or not the downstream arrangement involves substantial financial risk. The suggestion was made that the requirement that the contract "lasts at least one year" be reworded to be "is for a period of at least one year" to permit terminating the contract if the provider is not performing. The IG representative indicated an openness to this suggestion if the termination permitted is "termination for cause."

NO SWAPPING

The Federal proposal on "no swapping" for the first prong is at page 2 of **Attachment B**. This section of the proposal generated a lengthy discussion in which Committee Members raised following major concerns about the Federal proposal:

- The concepts of "tying two lines of business together" and "taking into account" other business between the providers are too broad and would prohibit many common negotiating practices that are not swaps intended to induce referrals or to be in return for Federal program business. Lack of clarity on this could increase nervousness among providers about their managed care relationships, even where there is no real anti-kickback concern.
- The proposed provision could have a "chilling effect" on arrangements intended to meet other public policy concerns; for example, it is increasingly common for States to require a plan or provider to accept Medicaid business or to provide services to the disabled as a condition for receiving other

State business (particularly State employee enrollees).

The Federal agencies indicated some openness to considering other language if it would meet their concerns. Some examples of bargaining given by Committee Members clearly would not meet the Federal agencies' concerns, they indicated. They clarified, for example, that the fact that Medicare could not be charged more under a Medicare risk contract than the capitated rate does not mean there is no reason for anti-kickback concerns about swapping where Medicare risk contracts and commercial business are included in the same arrangement--the promise of Medicare FFS business in the form of the retirees under an employee plan could be an inducement for a lower rate on commercial business if the provider bills directly for the Medicare FFS business and can control volume. One law enforcer noted that it seems there would be no legitimate reason in such situations for disclosing how many Medicare retirees are covered by the employer plan--if the negotiators are not discussing the FFS business, then they would not be basing their decision on it and would be protected. One provider representative indicated that providers necessarily must consider such things in order to evaluate the profitability of the arrangement.

Some Committee Members indicated they would want protection for situations where capitated rates for several lines of business are negotiated together and each rate is sufficient to cover the provider's fixed costs, but varying rates affecting the profit margin are negotiated for different lines of business in order to get the necessary volume. One Federal representative indicated he understood this concern.

On the third day of the meeting, some Committee Members offered the following modification of the no swapping provision (as a substitute for the entire no swapping provision at page 2 of the Federal proposal):

> An arrangement is not protected when it is intended to provide remuneration in return for or to induce the referral of Federal health care program (as defined in the Statute) fee-for-service business between the parties. The provider cannot shift the burden of such an arrangement to the extent that increased payments are claimed from a Federal health care program.

Federal concerns with this modification included the following:

- The second sentence should not limit the first, but should begin "In addition" as in the Federal proposal-- this is needed so that if costs increase, the arrangement would be outside of the safe harbor (although the Federal government would still have to prove its anti-kickback case).

- The first sentence would safe harbor an arrangement where a plan offered Medicare business (with a higher capitated rate) in exchange for a lower rate on commercial business; yet, even if such arrangements might not lead to increased Medicare FFS costs, they might violate other laws.
- If one rate is being subsidized by another rate, this could lead to higher costs in other Federal programs, such as the Office of Personnel Management's program for Federal employees, or could cause Medicare beneficiaries to pay coinsurance based on a fictional amount.
- In general, basing a pricing decision on Medicare FFS business gives a plan the benefit of business the plan is not paying for--the numbers of Medicare retirees "tagging along" could be significant, and, by paying coinsurance and deductibles for beneficiaries staying in the network, the plan is in effect "channeling" the Medicare population to the network.

Some Committee Members questioned whether there is an anti-kickback concern where a private pay capitated rate is higher than the Medicare rate. In response to a suggestion that the private pay rate could be remuneration for getting the Medicare business, some Committee Members noted that the provider would not have control over the amount of business and there would be no increased cost to Medicare. The Committee discussed whether concerns about negotiating practices violating other laws could be addressed in the preamble to the rule, rather than by limiting the safe harbor protection. Some Committee Members also suggested that the preamble should make it clear that merely including more than one line of business in an arrangement and having varying rates would not necessarily implicate the anti-kickback provisions.

The DOJ representative indicated that she would be comfortable with language somewhere between the Federal proposal and the proposed modification, but could not commit to this since the topic was the subject of some discussion in the interagency process. In talking about expanding the exception, the Federal government needs to consider the policy ramifications, she said. Safe harboring certain arrangements could be viewed as sanctioning them, she indicated, and therefore could affect conduct.

Provider groups indicated a concern with the suggestion that provider groups should not even know the numbers of Medicare retirees in a plan because this would make it difficult for them to evaluate profitability and because providers do not have much choice when plans tie lines of business together in one arrangement. One Member suggested that Committee Members develop specific examples of situations they believe do not raise anti-

kickback problems.

DEFINITIONS

The Federal proposal for definitions for the first prong is at page 2 of **Attachment B**. The following concerns were identified with respect to the proposed definition of "items or services":

- Limiting the services to "medical services" would exclude transportation that might be covered under Medicare (as part of the additional benefits offered) or under Medicaid.
- The term "marketing" needs to be clarified so it is not read as covering things like setting up a nurse line.

The Federal agencies indicated they would be open to some description other than medical, but definitely would not want to cover marketing in this safe harbor (although they were considering addressing it separately). The Committee later discussed the following option, developed at the September meeting:

> The services must be health services or reasonably related to the provision of health services (which would include patient education, attendant social services like case management, and disease management).

(Most Members had concurred in this option; a few had indicated concerns, as listed on page 15 of the minutes of the September meeting.) There was some discussion of why the Committee did not adopt a statutory definition of what items or services could be covered under Medicare. Problems identified with this approach were that 1) that one such definition is in the civil monetary penalty provisions and is not appropriate; 2) that definition covers some administrative services that the IG does not want covered; and 3) another definition might not cover managed care services such as disease management.

Some provider Members expressed concern that providers (downstream under the first prong) offering a capitated package of services that includes some administration should not have to worry about whether including the administrative services would take them out of the safe harbor. Examples included a hospital accepting a DRG rate, or a pharmacy benefit management company accepting a rate that covers costs of claims processing and drug utilization review that could not be desegregated from the cost of the prescriptions.

One Member suggested that, if the Committee adopts a definition different from existing definitions, the preamble should explain the connection and why those definitions were not adopted.

SECOND PRONG

GENERAL

The second part of the Federal proposal (**II. Managed Care Organizations Billing Medicare on Fee-For-Service Basis**) was referred to at the November meeting as the "second prong." This term was used at previous meetings to refer to the second part of section 216 (protection for remuneration pursuant to a written agreement between an organization and an individual or entity providing items or services, or a combination thereof, if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or combination thereof, which the individual or entity is obligated to provide). The Federal agencies explained that--

- the Federal proposal would broaden the concept of "obligated to provide" to cover referral services (under the HHS regulatory authority);
- the Federal agencies' openness to this expansion (as well as the expansion under the first prong) depends on the rule having a tight definition of "substantial financial risk"; and
- the Federal agencies tried to address consumer concerns by structuring the second prong so there would be no credit for underutilization, by defining "organization" to require that there be quality assurance and an appeal and grievance procedure; and by including some performance bonuses in the calculation of the numeric standard for substantial financial risk.

Some Committee Members noted that the importance of safe harbor protection under the second prong would be diminished if the first prong covers more entities and protects downstream arrangements, without requiring substantial financial risk. Committee Members did not disagree generally that the second prong is addressing arrangements where the Federal program is paying on an FFS basis.

"ORGANIZATION"

The Federal proposal definition of "organization" for the second prong is at page 3 of **Attachment B**. The Federal agencies explained that--

- the purpose in defining "organization" as a health plan is to deny protection to "free floaters" because, where there is not enough of a managed care context, it is too easy to

play with target levels to disguise an arrangement as substantial financial risk;

- the Federal agencies read the second prong as addressing legitimate managed care arrangements;
- section (F) of the proposed definition of "organization" is not necessarily limited to a capitation arrangement;
- section (H) means that at least 50% of the enrollees are not Medicare FFS beneficiaries;
- section (I) reflects the key thought that Medicare beneficiaries must be part of a legitimate managed care plan and not treated any differently from other enrollees, from the providers' point of view;
- it would be okay to have a separate rate for Medicare beneficiaries so long as 50% or more of these beneficiaries are enrolled in plans of covered entities under the first prong and so long as the separate rate is the same for the beneficiaries under the Medicare risk contract and those not under the Medicare risk contract (and other prong 2 requirements are met);
- a bundled rate would not necessarily be a managed care arrangement counteracting overutilization because, even if there is risk from the providers' viewpoint, there is no sensitivity to volume;
- while an inpatient DRG might reduce costs of inpatient services and hospital inpatient admissions would be tied to a spell of illness, a DRG would not speak to the number of outpatient services, so it would not assuage overutilization concerns;
- having a "gatekeeper" is an important control; and
- while it would not be okay to have a separate utilization target for Medicare beneficiaries, it may be okay, for example, to have a utilization target for stroke treatments; and
- an IPA could be a health plan if it met all the criteria.

Committee Members identified many concerns or questions, including the following:

- Whether Prescription Benefit Management companies would be covered as agents of employer health plans or as plans;
- What is imported into this definition from the existing safe harbor definition of "health plan";
- How copayments and deductibles would be treated under section (E);
- Whether section (E) would affect whether self-funded ERISA plans could qualify for protection (given that providers are more willing to insulate enrollees from liability if there is a reserve or reinsurance behind the plan);

- Whether ERISA plans would be covered even if they do not pay on a periodic basis as required by section (F) and, in general, what part of the payments, if any, could be paid not on a periodic basis;
- How could health plans that are directed to older populations (such as one offering post-acute, long-term care) meet the 50% requirement in section (H);
- What about utilization review targets directed at older populations;
- Whether any plan could meet section (I), given that plans do not have authority to bill for Medicare Part A services;
- Whether forcing providers to construct blended rates could lead to discrimination against Medicare patients since the resulting rates would be insufficient to cover the full cost of services to them;
- Whether the data exists to construct blended rates; and
- How to address risk sharing where there is no "health plan" involved.

One provider representative suggested that there should be protection for DRG rates or certain bundled rates where utilization concerns are addressed in other ways, especially for SNFs, which will now have to bill for a bundle of services and will have to enter into risk sharing with suppliers, etc. An IG representative indicated that utilization controls within an SNF would not control admissions and that extending the protection this way would be too complicated. He also noted that many services could be considered bundled (for example, a physician does not charge separately for tongue depressors). He indicated that the Federal agencies interpret the statutory language as ruling out providers as organizations. The Federal agencies indicated that DRGs have been around for a long time without being considered something that transforms a hospital into a managed care organization that must share risk.

A health plan representative noted that, in most instances, providers bill Medicare directly, so the proposal would require the health plans to restructure, that this would be resource intensive, and that Medicare rates may not be higher than what the plan pays. He expressed concern about the second prong of the proposal having this effect, in light of its limited application. Committee members also discussed the Medicare Carrier Manual provisions on assignment of claims and whether they would permit plans to bill.

One possible option for defining "organization" was developed by a caucus of Committee Members and was circulated on November 22, but was not discussed.

SUBSTANTIAL FINANCIAL RISK - Payment methodology standard

The Federal proposal for a "Payment Methodology Standard" (one of two ways a provider would be at "substantial financial risk under the proposal) is at page 4 of **Attachment B**. Clarifications with respect to this proposal included the following:

- Use of the term "full capitation" in section (i) of the proposal for a payment methodology standard would not preclude the use of reinsurance or taking capitation only for part of the services provided; if part of the services are "carved out" and paid on an FFS basis, however, then only the part that is capitated would be protected.
- By "inpatient case rate," the proposal means a hospital inpatient case rate like an inpatient DRG, where there is less risk of overutilization because of the magnitude of the services furnished (although the Federal agencies have only marginal confidence in inpatient hospital DRGs being enough of a risk indicator, in light of studies showing that hospital utilization is not fixed).
- While case rates may be okay in concept and the Federal agencies are not averse to considering them if the definition would give sufficient control, the Federal agencies are concerned that too much could be characterized as a case rate and that protecting case rates for outpatient services could lead to potential abuses.
- The Federal agencies still have concerns about the per diem provision in section (iv) and want to talk to providers about what controls prevent overutilization and how to construct a per diem exception with enough safeguards.
- While the Federal agencies recognize that bundling may be a partial solution to overutilization concerns, the problem is that there is no limit on the number of bundles.
- Sufficient historical data could be used, instead of an actuarial opinion, to meet the condition of setting reimbursement at "actuarially sound limits"--the point is that there must be something objective to ensure that there is a reasonable basis for the price; fair market value might not meet this test.

Comments about the proposal for a payment methodology standard included the following:

- In the real world, there may be no meaningful distinction between inpatient and outpatient services for purposes of a case rate (for example, one case rate might apply to a surgery service ordered, whether it is done on an inpatient or ambulatory basis).
- In rural areas, if a provider is paid at a case rate with no severity index (because it is simpler than a DRG that is adjusted for severity), there is more risk.

- There should be protection for case rates where the number of cases is not in the control of the provider.

SUBSTANTIAL FINANCIAL RISK - Numeric Standard

The Federal proposal for a numeric standard for a provider being at substantial financial risk is at pages 4-5 of **Attachment B**. The Committee identified the following as types of reimbursement that this standard would potentially protect: withholds, bonuses, some case rates, and some per diems.

The following was given as an example of how to calculate the risk percentage: if the target payment is $80, the minimum payment is $60, and the $20 withheld goes into risk pools ($5 for specialty services and $15 for hospital services) and if the provider would get all of the $20 back by hitting the proper target (expected utilization based on actuarially sound principles), the ratio would be $20 over $60 (33.3%) and the 20% standard would be met. If performance bonuses (i.e., non-utilization based bonuses) totaling $100 are expected to be earned by 75% of providers, this amount would be added into both the target payment and the minimum payment, so the ratio would be $20 over $160 (12.5%). In this calculation, it would not matter if the $20 were a penalty that the provider had to pay back instead of a withhold.

During discussion of this proposal, the Federal agencies indicated the following:

- The proposed numeric standard addresses the kickback concern of overutilization, so it was constructed to count risk where providers get "dinged" (penalized) for overutilization (except that some performance bonuses get added into the the calculation).
- The 20% figure was chosen based on the antitrust policy statement.
- The reference to "the 75th percentile of participating providers" in section (B)(ii)(c) may need to be changed since what was meant was that if 75% of the participating providers get the performance bonus, it would be added into both parts of the calculation.
- Some adjustment may be needed to address a possible conflict between the calculation, which includes a target payment based on a utilization target for an entire plan, and the limit to risk for items or services the individual or entity is "obligated to provide" (as defined elsewhere in the proposal).
- The Federal agencies had not felt comfortable with the option considered earlier of a standard that would be met by an actuarial opinion, given the other parts of their

proposal.

Committee Members raised the following major concerns/questions about the 20% figure specifically:

- How, if at all, is capital contribution taken into account;
- What about providers that cannot control utilization; and
- Could different percentages be established for different providers that have a different cost of doing business--different size, type, or profit margin.

There was considerable discussion about whether risks related to capital contribution are a type of risk that should be included in calculating substantial financial risk and about what Congress meant by listing "capital contribution" as a factor to be considered. One hospital representative pointed to legislation on provider-sponsored organizations that may be interpreted as requiring that affiliated providers have a stake in the organization because of the importance of aligning the incentives in managed care relationships. The Federal agencies indicated that they still had not had any specific proposals about how to take capital contributions into account and that they would be concerned if considering capital contributions added complications to the rule and made it harder to apply.

There was also considerable discussion about differences among providers and their profit margins and about what data was available to measure the differences. Committee Members generally acknowledged that providers and payors have a responsibility to come up with another acceptable mechanism for evaluating substantial financial risk and concurred in the suggestion that **different types of providers should submit data and proposals for percentages other than 20% that would be appropriate.**

Other concerns about the Federal proposal for a numeric standard (raised when it was first discussed) included that--

- The proposal does not even meet existing arrangements (since they are typically based on exceeding a target rather than on meeting a target);
- The proposal is not flexible enough to cover future arrangements; and
- Adding performance bonuses into both the target payment and the minimum payment could reduce the percentage and this would act as a disincentive for including performance bonuses (such as quality bonuses) in risk sharing arrangements.

In response to Federal concerns about actuarial opinions, one

health plan representative said he had consulted with someone from the American Academy of Actuaries about whether they could construct a standard to meet the goal of the exception (for example, substantial financial risk that would not have an incentive to overutilize) and was told that they could. He suggested basically the following as a third element for the substantial financial risk requirement in the second prong:

> If an independent organization develops an actuarial standard to apply, then an actuarial opinion applying that standard would meet the requirement for substantial financial risk.

After caucusing, some Committee Members outlined several proposed modifications to the Federal proposal on a numeric standard. They first proposed:

- Extending the numeric standard to count risk assumed not only in meeting the target, but in exceeding the target (lowering utilization), by changing the word "meeting" to "meeting or exceeding" in section (B)(ii)(a)(1);
- Changing the phrase in section (B)(ii)(a) "**target payment** is the fair market value payment established through arms length negotiations that will be earned by a provider" by inserting after "negotiations" the phrase "that can reasonably be expected to be earned"; and
- Deleting section (B)(ii)(a)(2).

One health plan representative explained that there is not a single actuarially sound utilization target, but a range of values that is reasonably expected, and that bonuses to provide greater efficiencies, tied to values within that range, are not just hypothetical amounts that would not provide meaningful incentives. In his opinion, the Federal proposal would lead to manipulation of the target. One Federal representative responded that something has to be there that acts as a "hammer" to control overutilization. He indicated that encouraging proper utilization is fine, but there must be a "stick" to control overutilization since the Federal government is giving up a criminal statute. Other Committee Members said that Congress intended to recognize incentives to control cost and quality, not just penalties for overutilizing and that the "hammer" for a provider that overutilizes is termination.

Another caucus proposal was that performance bonuses either--

> - should not be counted in the calculation at all (preferred option), or
> - should be included in the target payment and the minimum payment if most people get them, but if everybody does not get them, should be included only in the target payment.

The Federal agencies expressed the following concerns in response to these proposals:

- If performance bonuses that are earned by virtually all providers are not included in the calculation as the Federal agencies proposed, they could be used to offset risk for the cost or utilization of items or services so that the true risk is not really substantial enough to act as a disincentive to overutilization; and
- Adding such bonuses into the target payment in the calculation requires also adding them into the minimum payment because they are part of the total compensation.

The health plan representative's response to the second point was that meaningful bonuses (that only some providers earn) would not be part of the expected pay (and therefore should not be in the denominator) and that the option of including them in the target payment was intended to encourage use of quality bonuses.

One provider representative indicated that adding performance bonuses in both parts of the calculation effectively makes the 20% closer to the 25% in the physician incentive plan rule. Another commented that increased utilization is not always bad.

Additional concerns with or questions about the Federal proposal were identified, as follows:

- How can actuarial soundness be determined (particularly for small providers)?
- Is the standard inconsistent with the physician incentive plan rule?
- How is the 75% determined?
- Whether the formula approach is problematic because contracts are negotiated individually and the formula does not address where the individual provider is in terms of risk
- Whether the individual has sufficient control to affect utilization patterns with respect to bonuses that are set across a panel
- How would the formula apply to an incentive plan, such as that explained by one of the presenters, where there is a point system and bonuses are tied to achieving a certain number of points?

There was some discussion of whether an alternative way of treating performance bonuses (to make sure that they are not bonuses that virtually everyone would earn so they effectively reduce the percent of the total payment that is at risk) would be to "cap" them, by subtracting the first x percent of the bonus

that comes into the calculation as a performance bonus and adding in only what is above that percent. A consumer representative indicated a problem with placing a "cap" on performance bonuses because it might minimize the possibility for quality bonuses. Another Committee Member responded that the proposal would only limit what could be included in determining whether an arrangement is protected, not eliminate such bonuses altogether.

"OBLIGATED TO PROVIDE"

The Federal proposal on what services should be considered services the provider is "obligated to provide" is at page 5 of **Attachment B**. The Federal agencies explained that--

- They would be comfortable including referrals in the second prong (and in expanding the first prong) only if tight definitions of organization and substantial financial risk are adopted;
- The second bullet of this part of the proposal addresses "carve outs"--they are not covered because they are not part of the risk sharing arrangement; and
- The Federal parties might be open to considering bonuses or withholds that are tied to plan performance not related to referrals.

There was considerable discussion of the "carve out" provision and of how Medicare FFS business is billed in employer plans.

DOWNSTREAM PROVIDERS

The Federal proposal on downstream providers for the second prong is at pages 5-6 of **Attachment B**. Protection would be extended downstream in the second prong so long as both parties are at substantial financial risk, as illustrated in the example on page 6 of Attachment B.

One provider representative questioned whether, if the Committee comes up with an alternative to the 50% rule, the Committee could come up with an approach that would protect the arrangement between levels 3 and 4 in the example, in spite of level 3 (the IPA) receiving FFS payments. There was some discussion of whether such protection would depend on whether there was assurance that the FFS rate at level 3 would not influence level 4 because the level 4 rate is instead influenced by other capitated substantial financial risk business.

Another provider representative questioned the treatment of downstream providers in light of the proposed definition of, and the statutory use of, the term "organization."

DEFINITIONS

The Federal proposal for definitions for the second prong is at pages 6-7 of **Attachment B**. In addition to the written agreement requirements for the first prong, the written agreement for the second prong would have to "specify the methodology for determining compensation which is set in advance, is consistent with actuarially sound calculations in arms-length transactions, and is not determined in a manner that takes into account the number of Federal health care program fee-for-service beneficiaries being served under the agreement or under other agreements."

Committee Members raised concerns about the "take into account" language (similar to concerns about the "no swapping" provision), and about determining whether calculations are actuarially sound.

NEXT STEPS

The Committee set the following schedule:

- **By COB on December 9**, Committee Members will submit specific proposals for modifying the Federal proposal. Each proposal should have at least the same degree of specificity as the Federal proposal and should include an explanation of what concern is being addressed and how the proposal addresses that concern (and still meets the concerns reflected in the Federal proposal), with examples or supporting data, if possible. **Each proposal should be sent by facsimile both to Mac Thornton at 202-205-0604 and to Judy Ballard at 202-690-5863.**

- Proposals not submitted by December 9 will not be considered further.

- **By December 16** (the first day of the December meeting) the Federal agencies will respond with a revised document.

- At the December meeting, the Committee will discuss the revised proposal, proposed language for the preamble to the rule, and the terms of a potential Committee agreement.

The December meeting is scheduled for December 16-18 at the Holiday Inn Capitol, 555 C Street, S.W., Washington, D.C.

The Federal agencies indicated that if the Committee is close to achieving consensus at the December meeting, they would be willing to meet in January. If the Committee is not close to achieving consensus by December 18, no further meeting will be held. If a January meeting is held, it would be held January 20-22, since those are the dates that a meeting room at the Holiday Inn is available.

ATTACHMENT A - LIST OF PARTICIPANTS

Committee Members present for part or all of the meeting:

Candace Schaller, AAHP
Elise Smith, AHCA
Mary R. Grealy, AHA
Edward B. Hirshfeld, AMA
Brent Miller, AMGA
Susan E. Nestor, BCBSA
Charles P. Sabatino, CCQHC
Missy Shaffer, CCC
Laura Steeves Gogal, FAHS
Eddie Allen, HIMA
Stephen M. Spahr, NAMFCU
S. Lawrence Kocot, NACDS
Karen A. Morrissette, DOJ
Don Brain, IIAA/NAHU/NALU
D. McCarty Thornton, OIG/HHS
Michael Weiden, NRHA
J. Mark Waxman, TIPAAA

Alternates substituting for Committee Members:

Kathleen Fyffe, HIAA
Marjorie Powell, PhRMA
Jennifer Goodman, NASMD
Mary Beth Senkewicz, NAIC

Alternates attending and/or substituting for Committee Member for part of the meeting:

Mark Joffe, AAHP; Howard Sollins, AHCA; Kathy Nino, AMA; Mary L. Kuffner, AMGA; Bob Wallace, DOJ; Nancy Trenti, IIAA/NAHU/NALU; Douglas Guerdat, BCBSA; Mark H. Gallant, NACDS; Janet Stokes, IIAA/NAHU/NALU; Bonnie Stein, NAMFCU; Kevin McAnaney, OIG/HHS

ATTACHMENT B
SAFE HARBORS FOR MANAGED PLANS AND ASSOCIATED PROVIDERS WHICH ARE PROVIDING SERVICES TO MEDICARE AND MEDICAID BENEFICIARIES

I.
Managed Care Organizations under Medicare Capitation

(n) ***Price reductions offered to Medicare HMO risk contractors.*** "Remuneration" under the anti-kickback statute does not include any remuneration between an eligible organization under 1876 and an individual or entity ("provider"), subject to the standards below.

COVERED ENTITIES

- "Eligible organization under 1876," i.e, Federally qualified HMOs and competitive medical plans.

- Also, after January 1, 1998, any Medicare Part C health plan which receives a capitated payment from Medicare and which must have its total Medicare beneficiary cost sharing approved by HCFA under section 1854 of the Social Security Act. **(HHS Regulatory Authority)**[2]

"FIRST TIER" PROVIDERS

- Where the provider provides items or services directly, the eligible organization and the provider providing the items or services must have an agreement which:

    (A) is set out in writing and signed by both parties;
    (B) specifies the items and services covered by the agreement;
    (C) lasts at least one year; and
    (D) specifies that the provider cannot claim payment in any form from Medicare except as approved by HCFA.

[2] "HHS Regulatory Authority" issues are outside the scope of 216 of HIPAA. Rulemaking on such issues is governed by the APA notice and comment procedures, not the negotiated rulemaking procedures.

"DOWNSTREAM" PROVIDERS **(HHS Regulatory Authority)**

- An upstream and a downstream provider must have a contract which:

  (A) is set out in writing and signed by parties to the contract;
  (B) specifies the items and services covered by the agreement;
  (C) lasts at least one year; and
  (D) specifies that the provider cannot claim payment in any form from Medicare except as approved by HCFA.

NO SWAPPING

- In order to prevent the tying of two lines of business together where one line of business is accepted by a provider at a much reduced rate in order to get: (1) another line of business; (2) Medicare beneficiaries who would be billed on a fee for services basis or (3) Medicare beneficiaries whose reimbursement would be at a higher rate, arrangements must meet the following:

  - In negotiating the terms of the arrangement, neither the upstream provider nor the downstream provider takes into account other business between the parties that is not part of the arrangement. For example, if an arrangement is entered into with the understanding that referrals will be made of unrelated fee-for-service business, that arrangement is not protected. In addition, the provider cannot shift the burden of such an arrangement to the extent that increased payments are claimed from a Federal health care program.

DEFINITIONS

- For purposes of this paragraph, the definitions of the certain terms are set forth as follows:

  (i) **items or services** only includes medical items, devices, supplies or services paid for in whole or in part by a Federal health care program and provided to a health plan enrollee. For example, "items or services" does not include marketing services, pre-enrollment screening, or peer review.

II.
Managed Care Organizations Billing Medicare On Fee-For-Service Basis

(o) Managed care organization risk-sharing arrangements. "Remuneration" under the anti-kickback statute does not include risk sharing arrangements ("RSAs") between an organization and an individual or entity ("provider") which is at substantial financial risk ("SFR"), if requirements below are met.

"ORGANIZATION"

- The organization is a health plan which functions as part of a managed care system which provides basic and supplemental health services. The organization:

  (A) sets utilization goals to avoid inappropriate utilization;
  (B) has an operational utilization review program;
  (C) has a quality assurance program;
  (D) has grievance and hearing procedures;
  (E) protects members from incurring financial liability;
  (F) receives payment on a periodic basis that does not take into account the dates services are provided, the frequency or services, or the extent or kind of services provided;
  (G) has a written agreement with first tier providers;
  (H) has at least 50% non-Medicare beneficiaries; and
  (I) bills Medicare directly for any services provided to Medicare beneficiaries and does not treat Medicare beneficiaries any differently than its other enrollees when determining the utilization targets or payments to a provider (including any bonuses or withholds).

"SUBSTANTIAL FINANCIAL RISK" (SFR)

- RSAs must meet one of the following standards for SFR:

(A) **Payment Methodology Standard** -- a provider is at SFR if payments are made under any of the following:

(i) full capitation;
(ii) percentage of premium;
(iii) inpatient case rate; or
(iv) per diem (when the length of stay is not in the control of the provider).

the reimbursement under these arrangements must be set at actuarially sound limits.

(B) **Numeric Standard** -- a provider is at SFR if:

(i) the target payment is at least 20% greater than the minimum payment.[3]

(ii) Definitions

(a) **target payment** is the fair market value payment established through arms length negotiations that will be earned by a provider and that:

1. is dependent on the provider's meeting actuarially sound utilization targets, whether based on his/her own, a group's or the plan's utilization (or a combination thereof); and

2. does not include any bonus or fees which the provider may earn from reducing utilization below the utilization target level.

(b) **minimum payment** is the minimum amount that a provider is entitled to receive under the contract.

[3] The arrangement must ensure that the amount at risk, i.e. the bonus/withold, is earned by a provider in direct relation to the ratio of the actual to the target utilization

(c) the target fee and minimum fee both include any bonus for performance (examples: timely submission of paperwork, continuing medical education, meeting attendance) at a level achieved by the 75th percentile of participating providers.

"OBLIGATED TO PROVIDE"

- To fall within the exception, the RSA must be one for the cost or utilization of services, which the provider is "obligated to provide." This includes:

  (A) services provided directly by the provider and its employees;
  (B) services for which the provider is financially responsible but which are provided by subcontractors; and
  (C) services for which the provider makes referrals, if the provider is at SFR for those services. **(HHS Regulatory Authority)**

- To be protected, Federal program items and services must be a part of the RSA (i.e., no "carve outs"). In other words, the provider may not receive higher payment for Federal items or services as compared to other items or services under the RSA. For example, arrangements which carve out Medicare or Medicaid services where the provider bills Federal health care programs directly, on a fee-for-service basis, would not be protected. However, if the arrangement is such that the provider receives the same payment for Medicare beneficiaries as other patients in the same plan, the RSA includes the Medicare beneficiaries, and the organization bills Medicare, the arrangement would be protected.

DOWNSTREAM PROVIDERS

- Exception includes written agreements between upstream and downstream providers. However, in order to prevent fee-for-service kickbacks disguised as risk sharing arrangements by so-called "free floaters," downstream providers are only protected if they are paid on an SFR basis by another provider who is also paid on an SFR basis. In other words, contracts involving a provider which is not paid on an SFR basis are not protected for any party. For example:

(1) HMO (capitated)

levels 1 and 2 protected

(2) PHO (percentage of premium -- physician and hospital services)

levels 2 and 3 not protected

(3) IPA (fee for service) ("Free Floater")

levels 3 and 4 not protected

(4) Physician group (capitated)

levels 4 and 5 protected

(5) Physician (capitated)

DEFINITIONS

- **items or services** only includes medical items, devices, supplies or services paid for in whole or in part by a Federal health care program and provided to a health plan enrollee. For example, items or services does not include marketing services, pre-enrollment screening, or peer review.

- **the written agreement** between the organization and provider, and downstream contracts between providers must:

  (A) set out in writing and signed by the parties;
  (B) specify the items and services covered by the agreement;
  (C) specify the intervals at which distributions will be paid;
  (D) specify the formula for calculating incentives and penalties;
  (E) last at least one year; and
  (F) specify the methodology for determining compensation which is set in advance, is consistent with actuarially sound calculations in arms-length transactions, and is not determined in a manner that takes into account the number of Federal health care program fee-

for-service beneficiaries being served under the agreement or under other agreements.

NO SWAPPING

- In order to prevent the tying of two lines of business together where one line of business is accepted by a provider at a much reduced rate in order to get: (1) another line of business; (2) Medicare beneficiaries who would be billed on a fee for services basis or (3) Medicare beneficiaries whose reimbursement would be at a higher rate, RSAs must meet the following:

    - In negotiating the terms of the arrangement, neither the upstream provider nor the downstream provider takes into account other business between the parties that is not part of the arrangement. For example, if an arrangement is entered into with the understanding that referrals will be made of unrelated fee-for-service business, that arrangement is not protected. In addition, the provider cannot shift the burden of such an arrangement to the extent that increased payments are claimed from a Federal health care program.

ATTACHMENT C

ISSUES, QUESTIONS and CONCERNS regarding the Nov. 19, 1997 Proposal Submitted by Federal Government Representatives

BOTH PRONGS (GENERAL)

Need to address how relates to:
- CHAMPUS
- Medicaid

SECOND PRONG (GENERAL)

Are consumer issues sufficiently addressed?

Is capital contribution taken into account?

What formula reasonably protects prong 2 providers at SFR, without manipulation?

Does Medicare SELECT fit in Prong 2? No SFR?

FIRST PRONG (SPECIFIC)

COVERED ENTITIES

Would any 1903(m) plans be covered?

What about PACE plans?

Medicare MC demonstrations

NO SWAPPING

Clarify "taking into account" where fixed costs covered & varying rates for different lines of business - to get volume

Consider possible "chilling effect" on meeting other public policy concerns (e.g., Medicaid, disabled)

DEFINITION: Items or Services

Is limit to "medical" too narrow - e.g. what about transportation?

Similar issues for Medicaid (non-medical services)

Clarify marketing? Ex. Setting up a nurse line - medical

SECOND PRONG

"ORGANIZATION"

Are PBMs agent or plan

Clarify what's imported from safe harbor definition of health plan

(F) Will ERISA plans be covered --> don't pay on periodic basis

(H) What about health plans directed to older populations --> 50%

(I) : Clarification: Separate rate for Medicare beneficiaries is OK so long as 50% or more of beneficiaries are in section 1876 (or Medicare + Choice covered entities) and so long as the separate rate is the same for the beneficiaries under the Medicare risk K and those not under the Medicare K - same Prong 2 conditions apply

(I): Utilization Review targets directed at older populations

Do plans have authority to bill for PartA services
(I) --> no health plan can meet

Lumping rates together could lead to discrimination vs. Medicare

Is the data there [to construct blended rates]?

How to address risk sharing where not a "health plan" involved

(F) - periodic basis --> what portion of payments (some revenue might not meet)

(E) - clarify re: copayments & deductibles

(E) - look at effects of provision on ERISA

SUBSTANTIAL FINANCIAL RISK (SFR)- (A) Payment methodology standard

(A)(iv) Concerns re: per diem - construct enough safeguards

(A)(iii) Just hospital inpatient?

(iii) Consider whether a meaningful distinction: service ordered - no distinction between whether inpatient or outpatient

(iii) Consider case rate so long as number of cases not within control of provider

SFR - (B) Numeric Standard

Note: the arrangements the committee is trying to address with numeric standard:

withholds
bonuses
some case rates
some per diems

(i) Question re: 20%

What about capital cost?
Some providers cannot control utilization
Different cost of doing business - ask for information, e.g., profit margin
size, type, etc?

Other Concerns:

Does not even meet existing arrangements

What about future arrangements?

If formula includes target for entire plan, how does this fit with "obligated to provide" limit?

SFR - Proposal for new "3rd element"

If independent organization develops an actuarial standard to apply, have actuarial opinion, e.g. SFR that would not have incentive to over utilize

DOWNSTREAM PROVIDERS

Should we protect arrangement between levels 3 & 4 so long as level 4 rate not influenced by FFS payment to level 3 because rate at level 4 is set mostly for business where IPA (level 3) is at SFR (capped?)

Concern: treatment of downstream relation to definition of organization + statutory language

"take into account" problem

Is there something else besides 50%/blend to protect?

DEFINITIONS - Written Agreement:

(E) Suggest "for a term of " at least one year [so agreement could be terminated for cause

(F) Concerns:

- "actuarially sound" calculations - elusive standard

- "take into account" problem [same as for first prong/no swapping]

- all patients are FFS [at plan level in second prong] - talking about volume would technically violate - should be based on how provider paid